PCT/US

Serial No.: 10/009,151

Filed : Apr

: April 16, 2002

Page

: 2 of 13

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1-21. (Canceled)

- 22. (Withdrawn) A method for producing denatured lipoprotein, comprising: freezing a solution containing lipoprotein to produce a frozen solution; and melting the frozen solution to produce a solution containing denatured lipoprotein.
- 23. (Withdrawn) The method according to claim 22, wherein said denatured lipoprotein reacts with a DLH3 antibody which is yielded by hybridoma cell line, mouse-mouse hybridoma FOH1a/DLD3 (Deposit No. FERM BP-7171).
- 24. (Withdrawn) The method according to claim 22, wherein the lipoprotein is at least one selected from the group consisting of chyromicron, VLDL, LDL, Lp(a), HDL2 and HDL3.
 - 25. (Withdrawn) A denatured lipoprotein produced by the method according to claim 22.
- 26. (Withdrawn) The denatured lipoprotein according to claim 25, wherein said denatured lipoprotein reacts with a DLH3 antibody which is yielded by hybridoma cell line, mouse-mouse hybridoma FOH1a/DLD3 (Deposit No. FERM BP-7171).

Attorney's Docket No.: 13723-002001 / F 2000-38-Applicant: Takashi Shigematsu et al. PCT/US

Serial No.: 10/009,151

Filed : April 16, 2002

Page : 3 of 13

27. (Currently Amended) A method for producing a stabilized denatured lipoprotein standard, comprising:

freezing a first solution containing lipoprotein to produce a frozen solution of lipoprotein; melting the frozen solution to produce a melted solution of denatured lipoprotein; mixing a stabilizing agent with the melted solution to produce a second solution; and freeze-drying the melted second solution to produce a powder containing stabilized denatured lipoprotein in powder form; and

determining an amount of the denatured lipoprotein in the powder.

28. (Canceled)

- 29. (Previously Presented) The method according to claim 27, wherein the lipoprotein is at least one selected from the group consisting of chyromicron, VLDL, LDL, Lp(a), HDL2 and HDL3.
- 30. (Withdrawn) A stabilized denatured lipoprotein produced by the method according to claim 27.
- 31. (Withdrawn) The stabilized denatured lipoprotein according to claim 30, wherein said stabilized denatured lipoprotein reacts with a DLH3 antibody which is yielded by hybridoma cell line, mouse-mouse hybridoma FOH1a/DLD3 (Deposit No. FERM BP-7171).
 - 32. (Withdrawn) A method for producing stabilized denatured lipoprotein, comprising: freezing a solution containing lipoprotein to produce a frozen solution; melting the frozen solution to produce a solution containing denatured lipoprotein; adding a stabilizer to the solution; and freeze-drying the solution.

PCT/US

Serial No.: 10/009,151 Filed: April 16, 2002

Page :

Page : 4 of 13

33. (Withdrawn) The method according to claim 32, wherein said denatured lipoprotein reacts with a DLH3 antibody which is yielded by hybridoma cell line, mouse-mouse hybridoma FOH1a/DLD3 (Deposit No. FERM BP-7171).

- 34. (Withdrawn) The method according to claim 32, wherein the lipoprotein is at least one selected from the group consisting of chyromicron, VLDL, LDL, Lp(a), HDL2 and HDL3.
- 35. (Withdrawn) A stabilized denatured lipoprotein produced by the method according to claim 32.
- 36. (Withdrawn) The stabilized denatured lipoprotein according to claim 35, wherein said denatured lipoprotein reacts with a DLH3 antibody which is yielded by hybridoma cell line, mouse-mouse hybridoma FOH1a/DLD3 (Deposit No. FERM BP-7171).
- 37. (Withdrawn) A method for determining denatured lipoprotein in a sample, comprising:

selecting the denatured lipoprotein according to claim 25;
reacting the sample with an antibody which binds to the denatured lipoprotein;
measuring the reactivity of the antibody with the sample; and
comparing the reactivity with a calibration curve previously formed from the denatured
lipoprotein.

38. (Withdrawn) The method according to claim 37, wherein said determination is immunological determination.

Serial No.: 10/009,151 Filed: April 16, 2002

Page : 5 of 13

39. (Withdrawn) The method according to claim 38, wherein said immunological determination is selected from among radio immunoassay, enzyme immunoassay, fluoroimmunoassay, luminescent immunoassay, agglutination immunoassay, immunonephelometry, and nephelometric immunoassay.

- 40. (Withdrawn) The method according to claim 39, wherein said method for immunological determination is a competitive method or a sandwich method.
- 41. (Withdrawn) The method according to claim 37, wherein said denatured lipoprotein is a standard substance for determining denatured lipoprotein in blood or an experimental reagent for investigating the physiological role or the physiological activity of denatured lipoprotein.
- 42. (Withdrawn) A method for determining denatured lipoprotein in a sample, comprising:

selecting the stabilized denatured lipoprotein according to claim 30; reacting the sample with an antibody which binds to the denatured lipoprotein; measuring the reactivity of the antibody with the sample; and comparing the reactivity with a calibration curve previously formed from the denatured lipoprotein.

- 43. (Withdrawn) The method according to claim 42, wherein said determination is immunological determination.
- 44. (Withdrawn) The method according to claim 43, wherein said immunological determination is selected from among radio immunoassay, enzyme immunoassay, fluoroimmunoassay, luminescent immunoassay, agglutination immunoassay, immunonephelometry, and nephelometric immunoassay.

PCT/US

Serial No.: 10/009,151 : April 16, 2002

Filed

Page : 6 of 13

45. (Withdrawn) The method according to claim 44, wherein said method for immunological determination is a competitive method or a sandwich method.

- 46. (Withdrawn) The method according to claim 42, wherein said denatured lipoprotein is a standard substance for determining denatured lipoprotein in blood or an experimental reagent for investigating the physiological role or the physiological activity of denatured lipoprotein.
- 47. (Withdrawn) A method for determining denatured lipoprotein in a sample, selecting the stabilized denatured lipoprotein according to claim 35; comprising: reacting the sample with an antibody which binds to the denatured lipoprotein; measuring the reactivity of the antibody with the sample; and comparing the reactivity with a calibration curve previously formed from the denatured lipoprotein.
- 48. (Withdrawn) The method according to claim 47, wherein said determination is immunological determination.
- 49. (Withdrawn) The method according to claim 48, wherein said immunological determination is selected from among radio immunoassay, enzyme immunoassay, fluoroimmunoassay, luminescent immunoassay, agglutination immunoassay, immunonephelometry, and nephelometric immunoassay.
- 50. (Withdrawn) The method according to claim 49, wherein said method for immunological determination is a competitive method or a sandwich method.
- 51. (Withdrawn) The method according to claim 47, wherein said denatured lipoprotein is a standard substance for determining denatured lipoprotein in blood or an experimental reagent for investigating the physiological role or the physiological activity of denatured lipoprotein.

Serial No.: 10/009,151 : April 16, 2002 Filed

Page : 7 of 13

52. (Withdrawn) A reagent kit for determining denatured lipoprotein, comprising the denatured lipoprotein according to claim 25 as a standard substance.

- 53. (Withdrawn) A reagent kit for determining denatured lipoprotein, comprising the stabilized denatured lipoprotein according to claim 30 as a standard substance.
- 54. (Withdrawn) A reagent kit for determining denatured lipoprotein, comprising the stabilized denatured lipoprotein according to claim 35 as a standard substance.
- 55. (Withdrawn) A reagent kit for determining denatured lipoprotein, comprising a diluting liquid for a sample, a solid phase formed by immobilizing an antibody, a reaction buffer, a washing solution, a labeled secondary antibody, a detecting reagent, and the whole or part of the denatured lipoprotein set forth in claim 25 as a standard substance as component elements.
- 56. (Withdrawn) A reagent kit for determining denatured lipoprotein, comprising a diluting liquid for a sample, a solid phase formed by immobilizing an antibody, a reaction buffer, a washing solution, a labeled secondary antibody, a detecting reagent, and the whole or part of the stabilized denatured lipoprotein set forth in claim 30 as a standard substance as component elements.
- 57. (Withdrawn) A reagent kit for determining denatured lipoprotein, comprising a diluting liquid for a sample, a solid phase formed by immobilizing an antibody, a reaction buffer, a washing solution, a labeled secondary antibody, a detecting reagent, and the whole or part of the stabilized denatured lipoprotein set forth in claim 35 as a standard substance as component elements.

58. (Cancelled)

Serial No. : 10/009,151

Filed : April 16, 2002

Page : 8 of 13

form.

59. (Previously presented) The method according to claim 27, further comprising, preceding the freezing step, adding an anti-coagulant to the solution containing lipoprotein.

60-61. (Canceled)

- 62. (Previously Presented) The method according to claim 59, wherein the solution containing lipoprotein is plasma.
- 63. (Previously Presented) The method according to claim 27, wherein the solution containing lipoprotein is serum.
- 64. (Previously Presented) The method according to claim 27, wherein the solution containing lipoprotein is anticoagulant-containing plasma.
- 65. (New) The method of claim 27, further comprising determining an amount of the denatured lipoprotein in the powder.
- 66. (New) A method for producing a stabilized denatured lipoprotein standard, consisting essential of:

freezing a first solution containing lipoprotein to produce a frozen solution of lipoprotein; melting the frozen solution to produce a melted solution of denatured lipoprotein; mixing a stabilizing agent with the melted solution to produce a second solution; and freeze-drying the second solution to produce stabilized denatured lipoprotein in powder

Applicant: Takashi Shigematsu et al.

Attorney's Docket No.: 13723-002001 / F 2000-38-Serial No.: 10/009,151

PCT/US

Serial No.: 10/009,151 Filed: April 16, 2002

Page : 9 of 13

67. (New) A method for producing a stabilized denatured oxidized lipoprotein standard, comprising:

freezing a first solution containing lipoprotein to produce a frozen solution of lipoprotein; melting the frozen solution to produce a melted solution of denatured lipoprotein; mixing a stabilizing agent with the melted solution to produce a second solution; freeze-drying the second solution to produce a powder containing stabilized denatured oxidized lipoprotein that binds to antibody DLH3; and

determining an amount of the denatured lipoprotein in the powder.